REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the claims

Claims 2, 16, 19-23, and 40-93 are canceled.

Claims 1, 11, 13 and 15 are currently amended. The amendments add no new matter. Claims 1, 11 and 15 were amended to specify surface stabilizers, and claim 13 was amended to replace trademark names with their generic names.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 3-15, 17, 18, 24-39 are now pending in this application.

II. Amendments to the specification

The specification was amended to correct the priority claim and to include the generic names of some compounds listed by trademark names. The amendments introduce no new matter.

III. Claim rejections – non-statutory obviousness-type double patenting

Applicants acknowledge the non-statutory, obviousness-type double patenting rejection presented by the Examiner with respect to claims 1, 3-15, 17, 18, and 24-39. However, Applicants wish to wait to address this rejection once the claims are found allowable.

IV. Claim rejections – 35 U.S.C. § 102(e)

Claims 1, 3-15 and 29-39 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,969,529 to Bosch *et al.* (hereinafter the '529 Patent). The Office Action asserts that the '529 Patent teaches "compositions comprising nifedipine and a surface stabilizer" in the "same particle size range," and that "[i]n particular, example 2 recites vinyl pyrrolidone and vinyl acetate copolymer." (Office Action at page 5). Applicants respectfully traverse the rejection.

"A claim in anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (MPEP § 2131). Also, the "identical invention must be shown in as complete detail as is contained in the ... claim." (*Id.*) Furthermore, if an independent claim is not anticipated, claims depending therefrom are not anticipated. Here, the cited reference does not include, either expressly or inherently, each and every element of claim 1. Thus, claims 1, 3-15 and 29-39 are not anticipated by the '529 Patent.

Independent claim 1 has been amended to recite "wherein the surface stabilizer *is not* selected from vinyl pyrrolidone, vinyl acetate copolymer, poloxamer and PLURONIC F68." This amendment renders the rejection under 35 U.S.C. § 102(e) moot, as each and every element of the claim has not been met by the '529 Patent. Specifically, the '529 Patent does not disclose, either expressly or inherently, a nanoparticulate nifedipine composition including a surface stabilizer other than vinyl pyrrolidone or vinyl acetate copolymer. In contrast, claims of the present application are directed to compositions including surface stabilizers which are not vinyl pyrrolidone or vinyl acetate copolymer.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

V. Claim rejections – 35 U.S.C. § 102(b)

Claims 1, 3-8, 10-12, 14 and 29-39 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kim *et al.*, Br. J. Pharmacology (1997) 120: 399-404 (hereinafter "Kim *et al.*"). Applicants respectfully traverse the rejection.

Similar to the '529 Patent, the cited reference Kim *et al.* does not include, either expressly or inherently, each and every element of claim 1. Thus, claims 1, 3-8, 10-12, 14 and 29-39 are not anticipated by Kim *et al.*

As described above, claim 1 has been amended to recite "at least one surface stabilizer, wherein the surface stabilizer *is not* selected from ... poloxamer and PLURONIC F68." As described in the Office Action, Kim *et al.* teach "orally administered nifedipine particles treated with Pluronic® F68 (which is also known as poloxamer, recited in claim 11)...." However, Kim *et al.* do not disclose, either expressly or inherently nifedipine particles with stabilizers *other than* poloxamer (Pluronic F68). In contrast, the claimed compositions are directed to nifedipine particles having one or more surface stabilizers, *none* of which are poloxamer (*i.e.*, *not* Pluronic F68). Thus, Kim *et al.* do not disclose, either expressly or inherently, each and every element of claim 1.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

VI. Claim rejections – 35 U.S.C. § 103(a)

Claims 17, 18 and 24-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kim *et al*, in view of U.S. 4,814,175 (the '175 Patent) or U.S. 6,969,529 (the '529 Patent) in view of U.S. 4,814,175.

As described in the Office Action, a showing of common ownership between the '529 Patent and the present application will preclude a rejection under 35 U.S.C. § 103(a) based on the '529 Patent (Office Action at page 4).

The present application, 10/712,259, and the '529 Patent are both owned by Elan Pharma International, Ltd. or were subject to an obligation of assignment to Elan Pharma International, Ltd. at the time the invention of 10/712,259 was made. (*See e.g.*, MPEP 706.02(l)(2)). (*See* Exhibit B, Statement Concerning Common Ownership). Thus, the '529 Patent is disqualified as prior art under 35 U.S.C. § 103(c).

Referring to the combination of Kim *et al.* and the '175 Patent, Applicant respectfully traverses the rejection.

No reason has been identified, either in the references or in the Office Action, why one of skill in the art would have combined the disparate elements of the cited references in the manner claimed. (*See* U.S. PTO Memorandum dated May 3, 2007, re: Supreme Court Decision on *KSR Int'l. Co. v. Teleflex, Inc.*, stating that "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, *it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed*."). And as noted by the Supreme Court in KSR, *"[t]o facilitate review, this analysis should be made explicit.*" (U.S. PTO Memorandum citing KSR, citation omitted).

As described above, claim 1 has been amended to recite "at least one surface stabilizer, wherein the surface stabilizer *is not* selected from ... poloxamer and PLURONIC F68." Kim *et al.* disclose nifedipine particles with only poloxamer (*i.e.*, Pluronic® F68) as a stabilizer. No other stabilizers are mentioned.

The '175 Patent does not teach nanoparticles, stabilizers, or stabilized nanoparticles. For example, the '175 Patent does not disclose or suggest crystalline nanoparticles comprising nifedipine. Rather, the '175 Patent is directed to granulated formulations of nifedipine and a β-blocker (*i.e.*, mepindolol). The specification of the '175 Patent additionally describes that the nifedipine particles used to make the granulated compositions range in size from "10-50 μm, preferably 15-50 μm" ('175 Patent at col. 1, line 44). That is, the nifedipine particles taught in the '175 Patent are over an order of magnitude larger than those claimed in the present application.

The '175 Patent is additionally deficient in that it does not disclose or suggest the use of surface stabilizers for nanoparitcles. While the '175 Patent provides a list of auxiliary agents and fillers (*see e.g.*, column 1, lines 46-47, 50-68, continuing to col. 2, lines 1-2), there is no reason one of ordinary skill or creativity would consider combining such auxiliary agents and fillers, *for use as surface stabilizers*, with crystalline nifedipine particles to derive the claimed compositions, especially in light of the preparations taught by Kim *et al.*, which include only Pluronic F68 as a surface stabilizer. Simply, the '175 Patent does not teach nanoparticles, stabilizers, or stabilized nanoparticles and Kim *et al.*, teach only one stabilizer, poloxamer (Pluronic F68).

Accordingly, because each and every element of the claims are neither taught nor suggested by the cited references, and because no reason has been provided as to why one of ordinary skill and creativity would combine the different elements of these reference in the manner claimed, the cited references do not render the present claims obvious.

Thus, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

VII. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Dec 11, 2007 By _____

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717